

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: Public Law 92-218, as amended		
2. Request for Proposal (RFP) Number: N02-CN-15000-18	3. Issue Date: April 26, 2011	4. Set Aside: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes See Part IV Section L
5. Title : Technical Information Research Resources for Cancer Preventive Agent Development		
6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6026 6120 Executive Boulevard, MSC 7195 Bethesda, MD 20892-7195		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 PM local time on Tuesday, May 31, 2011 . Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Elaine M. Hochman PHONE: 301-435-3832 e-MAIL: eh28f@nih.gov OR hochmasu@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Elaine M. Hochman Contracting Officer Representative Office of Acquisitions National Cancer Institute

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this acquisition is to provide a variety of critical cancer prevention information management functions necessary to support the identification, development, and qualification of potential cancer preventive agents for investigational new drug (IND) applications to the Food and Drug Administration (FDA) for clinical trials.

ARTICLE B.2. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71 (June 2010) - WITH OPTIONS

- a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is \$ _____.
- b. The estimated cost of this contract is \$ _____.
- c. The fixed fee for this contract is \$ _____. For level of effort contracts: The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment of fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated March 10, 2011, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic versions, 1 hard copy (printed) of the following reports will be required as follows:

1. Quarterly Progress Report

One printed and PDF electronic file shall be due on or before the 15th calendar day following the end of each reporting period, to include the following:

- (a) Summary of progress in the past quarter in each task area.
- (b) Discussion of current or potential problem areas.
- (c) Suggestions for solutions to problems and operational improvements.
- (d) Discussion of progress, accomplishments, and plans for future work.

2. Draft Final Report

Similar to the quarterly report in format, but covering the entire project period. One printed and PDF electronic file of the draft final report shall be delivered 60 calendar days prior to the expiration date of the contract. The Contracting Officer's Technical Representative (COTR) will review the draft report and provide the Contracting Officer with comments within 25 calendar days of receipt.

3. Final Report

The contractor shall provide the final report (one printed and PDF electronic file) with corrections as noted in the draft final on or before the expiration date of the contract.

4. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

Other Technical Reporting Requirements

1. Agent Development Information Databases

One electronic copy (Adobe PDF files format submitted on CD-ROM) updated semi-annually:

- Test data summary (listing of all records in the database with agent name and agent testing status indexes)
- Preclinical test results summary
- Clinical data summary (listing of all records in the clinical databases with indexes by agent name, investigator, etc.)
- Contract summaries (preclinical and clinical)

2. Summaries, Presentations, and Overviews

- Prepare class studies to identify agents (up to 3 per year); prepare structure-activity studies (up to 5 per year); prepare worksheets (up to 50 per year)
- Prepared comprehensive ranking and recommendations for testing summaries (2 each per year)
- Prepare sections of INDs (3-5 per year; up to 25 documents), annual reports on INDs (up to 30 per year)
- Prepare presentation graphics (Powerpoint -primarily, but infrequently other formats as needed, approximately 6 sets on different topics)
- Written summaries of literature research and other written summaries relevant to chemopreventive agent development (approximately 6 per year)-in printed and electronic copies (as above format)

3. **Scientific and quality assurance review of technical reports** (up to 50 per year)
 - Summary itemizing deficiencies and corrections that are needed
4. **Chemoprevention agent development plans (5-7 per year, estimated) and initial worksheets**
 - Draft and final plans (within 6 weeks of assignment)
 - Worksheets for potential new agents (approximately 50 per year)
5. **Review and document new assay, models, intermediate endpoints being considered for use by CADRG testing program.**
6. **Investigational Drug Brochures (2 new brochures per year)**
 - Draft and final plans (within 12 weeks of assignment)
 - Updates of existing Investigational Drug Brochures (3 annually, with 12 weeks of assignment)
7. **Chemoprevention Clinical Trials Consortia support**
 - Prepare 5 agent announcements 2 times per year using existing documentation
 - Prepare background information about agents in unsolicited letters of intent (20 per year)
 - Prepare scientific reviews for concepts, etc. for Protocol Information Office (120 per year)
8. **DCP Management and Administrative Committee and External Steering Committee meeting support**
 - Prepare agenda, presentation and handout materials for Committee meetings (6 per year, estimated)
 - Prepare meeting summaries, and planning documents for the meetings
9. **PREVENT application review**
 - Prepare review materials, scoresheets and other documents for reviewers
 - Provide logistical (other than travel) support for reviewers (estimated 15 per review)
 - Provide written summaries of proposed projects and draft meeting minutes for approval

b. Other Reports/Deliverables

1. Information Security and Physical Access Reporting Requirements

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

a. Roster of Employees Requiring Suitability Investigations

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. IT Security Plan (IT-SP)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-SP within thirty (30) days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

(Reference subparagraph D.c.1. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

c. IT Risk Assessment (IT-RA)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

The Contractor shall update the IT-RA on an annual basis.

(Reference subparagraph D.c.2. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

d. FIPS 199 Assessment

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

(Reference subparagraph D.c.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

e. IT Security Certification and Accreditation (IT-SC&A)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

The Contractor shall perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid.

(Reference subparagraph D.c.4. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

f. Reporting of New and Departing Employees

The Contractor shall notify the Contracting Officer's Technical Representative (COTR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

- a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
- b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR and/or Contracting Officer upon request.

(Reference subparagraph E.3.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

g. Contractor - Employee Non-Disclosure Agreement(s)

The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>.

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

h. Vulnerability Scanning Reports

The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under separate cover on a monthly basis.

(Reference subparagraph E.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

2. Section 508 Annual Report

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: <http://www.hhs.gov/od> under "Vendor Information and Documents."

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Contracting Officer's Technical Representative (COTR) is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
Chemopreventive Agent Development Research Group, Division of Cancer Prevention
National Cancer Institute, Executive Plaza North, Room ____
6130 Executive Boulevard, MSC 7322, Bethesda MD 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from September 30, 2011 through September 29, 2018.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

ITEM	DESCRIPTION	QUANTITY	DELIVERY SCHEDULE
General Deliverables			
1	Quarterly Progress Report	1 PDF File (COTR) & Original hardcopy (CO)	Due 15 calendar days after end of reporting period
2	Draft Final Report	1 PDF File (COTR) & Original hardcopy (CO)	60 Calendar Days prior to contract completion
3	Final Report	1 PDF File (COTR) & Original hardcopy (CO)	Due on or before contract completion date
Task Area #1 Cancer Preventive Agent Identification, Documentation and Prioritization			
4	Updates of Agent Development Information Databases (See SOW Task Area #1, item 1)	1 PDF File (COTR)	Quarterly
5	Prepare class studies (up to 3 per year) (See SOW Task Area #1, item #2)	1 PDF File (COTR)	As requested by COTR
6	Prepare structure/activity Studies, (See SOW Task Area #1, item #3)	1 PDF File (COTR)	As requested by COTR
7	Document candidate agents (See SOW Task Area #1, item #4)	1 PDF File COTR	Twice per year
8	Document ranking of agents for screening and testing (See SOW Task Area #1, item #5)	1 PDF File (COTR)	Twice per year
9	Prepare Worksheets (up to 50 per year) and update with new information (See SOW Task Area #1, items # 6 and #7)	1 PDF File (COTR)	As requested by COTR
10	Provide status reports of agent development to COTR. (See SOW Task Area #1, item # 8)	1 PDF File (COTR)	As requested by COTR
11	Prepare detailed meeting minutes from External Steering Working Group and Special Emphasis Panel Meetings (See SOW Task Area #1, item #8)	1 PDF File (COTR)	Meeting minutes due 14 calendar days after meeting

ITEM	DESCRIPTION	QUANTITY	DELIVERY SCHEDULE
Task Area #2: Cancer Preventive Agent Data and Report Analysis, Status, Documentation			
12	Prepare Gantt chart timeline updates for agents (See SOW Task Area #2, item #2)	1 Online	Update Quarterly
13	Prepare up-to-date reports summarizing completed studies (See SOW Task Area #2, item #4)	1 PDF File (COTR)	Due 60 days after receipt of Final Report
14	Provide scientific reviews of Draft Final Reports (See SOW Task Area #2, item #4)	Email COTR	Due 30 days after Draft Final Report received
15	Document new assays, models and intermediate endpoints being considered (See SOW Task Area #2, item #5)	1 PDF File (COTR)	As requested by COTR
16	Prepare summaries, reviews, and presentation graphics (6 sets per year) (See SOW Task Area #2, item #6)	PDF files and Powerpoint slides (COTR)	As requested by COTR
17	Provide content (Draft Documents) for up to 5 INDs per year (See SOW Task Area #2, item #9)	1 PDF File (COTR)	As requested by COTR
18	Prepare summaries for meetings with FDA, scientific meetings, and internal DCP or NCI meetings (See SOW Task Area #2, item #7)	1 PDF File (COTR)	As requested by COTR
19	Draft and/or edit reviews/studies including preparation of graphics for publication (6 per year) (See SOW Task Area #2, item #6)	MS Word documents COTR	As requested by COTR
20	Prepare and update Clinical Development Plans (See SOW Task Area #2, item #8)	1 PDF File (COTR)	As requested by COTR, and annually within 6 weeks of assignment
21	Prepare content (draft documents) for Investigational Drug Brochures and updates (See SOW Task Area #2, item #9)	1 PDF File (COTR)	As requested by COTR, within 12 weeks of assignment
22	Presentations for DCP Management & Administrative Committee (See SOW Task Area #2, item #12)	Powerpoint and Handouts (COTR)	As requested by COTR
23	Prepare clinical consortia agent announcements using existing documentation (See SOW Task Area #2, item #13)	PDF Files (COTR)	As requested by COTR
24	Prepare background information about agents in unsolicited letters of intent (about 20 per year) (See SOW Task Area #2, item #13)	PDF Files (COTR)	As requested by COTR
25	Perform Scientific reviews for concepts, Letters of Intent, protocols, etc. for Protocol Information Office (See SOW Task Area #2, item #14)	PDF Files (COTR)	As requested by COTR, within 1 week of assignment
26	Provide technical information for workshops on chemopreventive topics, including program planning, speaker suggestions, implementation and recording (See SOW Task Area #2, item #15)	PDF Files and email (COTR)	As requested by COTR
27	Provide technical information support for Special Emphasis Panel, including abstracting applications, meeting planning and documentation (2 per year) (See SOW Task Area #2, item #16)	PDF Files (COTR)	As requested by COTR

ITEM	DESCRIPTION	QUANTITY		DELIVERY SCHEDULE
28	Updated Active Agent Database Table (See SOW Task Area #2, item #17(c))	Compact Disk File, or download from Contractor TBD by COTR	1 st of each Month	
29	Provide Quality Assurance Audits (See SOW Task Area #2, item #17(d))	PDF Files (COTR)	15 th of the month following the quarter	
30	Prepare an SOP for updating and maintaining the " CADRG Preclinical Testing Progress for Active Agents" Databases (See SOW Task Area #2, item #17(e))	PDF File (COTR)	Due 90 days after award	
31	Provide user documentation and training for " CADRG Preclinical Testing Progress for Active Agents" Databases (up to 2 per year) (See SOW Task Area #2, item #17(f))	PDF File (COTR)	As requested by COTR	
Task Area # 4 - General Tasks				
32	Standard Operating Procedures for all functions in the Statement of Work (SOW) (See SOW Task Area #4, item #2)	PDF File (COTR)	Due 120 days after contract award	
33	Provide edited documents generated by CADRG or other DCP groups (See SOW Task Area #4, item #3)	Word and PDF Files (COTR)	As requested by COTR	
34	Written plan for Quality Assurance and Quality Control of data and procedures described in the SOW (See SOW Task Area #4, item #7(a))	PDF File (COTR)	Due 60 days after contract award	
35	Procedural Manual for Technical Information (See SOW Task Area #4, item #7(a))	PDF File (COTR)	Due 90 days after contract award	
36	Transition Plan (See SOW Task Area #4, item #7(c))	PDF File (COTR)	60 days prior to expiration date of contract	
37	Master List Agent Databases (See SOW Task Area #4, item #7(d))	PDF File (COTR)	As directed by COTR	
Information Security Deliverables				
38	Roster of Employees requiring Suitability Investigations	1 PDF File (COTR) & Original hardcopy (CO)	14 calendar days after contract award	
39	Investigation Security Plan (IT-SP)	1 PDF File (COTR) & Original hardcopy (CO)	30 days after contract award	
40	IT Risk Assessment (IT-RA)	1 PDF File (COTR) & Original hardcopy (CO)	Within 30 days after contract award and updated on an annual basis	
41	FIPS 199 Assessment	1 PDF File (COTR) & Original hardcopy (CO)	Within 30 days after contract award	

ITEM	DESCRIPTION	QUANTITY	DELIVERY SCHEDULE
42	IT Security Certification and Accreditation (IT-SC&A)	1 PDF File (COTR) & Original hardcopy (CO)	Within 3 months after contract award
43	Reporting of new and Departing Employees	1 PDF File (COTR) & Original hardcopy (CO)	Within 5 days of staffing changes
44	Contractor - Employee Non-Disclosure Agreement(s)	1 original to COTR	Prior to commencement of work on contract
45	Vulnerability Scanning Reports	1 PDF File (COTR)	Monthly Basis (10 calendar days following end of each reporting period)
46	Information Security Training Report	1 PDF File (COTR) & Original hardcopy (CO)	Submitted before performing work on the contract
47	Section 508 Annual Report	1 PDF File (COTR) & Original hardcopy (CO)	See Section H
48	Section 508 conformance Certification	Original hardcopy (CO)	See Section H

b. Copies of reports shall be delivered to the following addresses:

Addressee	Deliverable Item No	Quantity
Contracting Officer's Technical Representative (COTR) [To be named] Chemopreventive Agent Development Research Group Division of Cancer Prevention, National Cancer Institute Executive Plaza North, Room _____ 6130 Executive Boulevard, MSC 7322 Bethesda MD 20892 Express/Direct Delivery Service: Rockville MD 20852 (remove MSC 7322) E-mail address to be provided	1 - 11 13 - 48	see quantity for each item above
Contracting Officer (CO) [To be named] Office of Acquisitions (OA) National Cancer Institute Executive Plaza South, Suite 600, Room _____ 6120 Executive Boulevard, MSC 7195 Bethesda MD 20892 Express/Direct Delivery Service: Rockville MD 20852 (remove MSC 7195) E-mail address to be provided	1, 2, 3, 38, 39, 40, 41, 42, 43, 46, 47, 48	see quantity for each item above
Online	12	see item above

ARTICLE F.3. LEVEL OF EFFORT

- a. During the period of performance of this contract, the Contractor shall provide **20,000** direct labor hours each year, for a total of **140,000** hours over the seven years. The labor hours exclude vacation, holiday, and sick leave. These labor hours exclude subcontractor labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total Hours All 7 Years
Professional	3,000	3,000	3,000	3,000	3,000	3,000	3,000	21,000
Professional Support	3,500	3,500	3,500	3,500	3,500	3,500	3,500	24,500
Administrative Support	7,500	7,500	7,500	7,500	7,500	7,500	7,500	52,500
Other Support	6,000	6,000	6,000	6,000	6,000	6,000	6,000	42,200
Total Hours	20,000	20,000	20,000	20,000	20,000	20,000	20,000	140,000

Annual Optional Labor Hours

If additional optional hours are required, during the period of performance of this contract, the Contractor shall provide **5,000** direct labor hours each year, for a total of **35,000**, if each additional Labor Hour option is exercised. The labor hours exclude vacation, holiday, and sick leave. These labor hours exclude subcontractor labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1 - Option 1A	Year 2 - Option 2A	Year 3 - Option 3A	Year 4 - Option 4A	Year 5 - Option 5A	Year 6 - Option 6A	Year 7 - Option 7A	Total Option Hours All 7 Years
Professional	750	750	750	750	750	750	750	5,250
Professional Support	875	875	875	875	875	875	875	6,125
Administrative Support	1,875	1,875	1,875	1,875	1,875	1,875	1,875	13,125
Other Support	1,500	1,500	1,500	1,500	1,500	1,500	1,500	10,500
Total Hours	5,000	5,000	5,000	5,000	5,000	5,000	5,000	35,000

- b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 110% of the total direct labor Hours specified herein are furnished.
- c. In the event fewer Hours than the minimum specified number of direct labor Hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of Hours by which the number of direct labor Hours furnished is less than the number of direct labor Hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The following Contracting Officer's Technical Representative (COTR) will represent the Government for the purpose of this contract:

To be specified prior to award

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COTR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

- b. One copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer (to be named)
Office of Acquisitions (OA)
National Cancer Institute
Executive Plaza South Room ____
6120 Executive Boulevard MSC 7195
Bethesda MD 20892- 7195

E-Mail: (electronic submission TBD at time of award)

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch B - ncibranchbinvoices@mail.nih.gov .

- c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - e. Invoice Matching Option. This contract requires a two-way match.
 - f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared as TBD at time of award .

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<https://www.cpars.csd.disa.mil>

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by authorities to be inappropriate for such distribution.

ARTICLE H.3. PRESS RELEASES

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.4. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

The Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.5. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.6. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-6, Option for Increased Quantity set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.7. INFORMATION AND PHYSICAL ACCESS SECURITY

A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
 1. HHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/121504.html>)
 2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (<http://www.hhs.gov/ohr/manual/pssh.pdf>)
 3. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
 4. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: <http://ocio.nih.gov/docs/public/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations, HHSAR 352.239-70, (January 2010)

- a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows Vista™, including desktops and laptops - regardless of function - but not including servers.
- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://nvd.nist.gov/validation.cfm>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.
- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (see <http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. Standard for Encryption language, HHSAR 352.239-71, (January 2010)

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
 - 1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.
 - 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 - 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
 - a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
 - iii. HHS-OCIO Information Systems Security and Privacy Policy.
 2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
 3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
 4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

- b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Technical Representative (COTR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COTR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.
- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
 - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

E. Additional NIH Requirements**1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)****a. Information Type:**

☐ Administrative, Management and Support Information:

☒ Mission Based Information:

D.19. Scientific and Technical Research

b. Security Categories and Levels:

Confidentiality Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

Overall Level: ☐ Low ☒ Moderate ☐ High

- c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a) (4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COTR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at Secure One HHS Memorandum on Role-Based Training Requirement.

For additional information see the following: <http://ocio.nih.gov/security/security-communicating.htm#RoleBased>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COTR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (<http://ocio.nih.gov/security/nihitrob.html>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

3. PERSONNEL SECURITY RESPONSIBILITIES

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COTR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COTR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COTR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**
The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>.

A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COTR prior to performing any work under this acquisition.

4. VULNERABILITY SCANNING REQUIREMENTS

This acquisition requires the Contractor to host an NIH webpage or database. The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (<http://www.sans.org/top20/?ref=3706#w1>). The Contractor shall report the results of these scans to the Project Officer/COTR on a monthly basis, with reports due 10 calendar days following the end of each reporting period. The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

ARTICLE H.8. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.
- b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).

[(End of HHSAR 352.239-73(b))]

- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a

timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

(to be completed at time of award)

[End of HHSAR 352.239-73(c)]

ARTICLE H.9. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.11. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.12. SHARING RESEARCH DATA

he data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at <http://www.hhs.gov/ocr/>). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (October 2010); **52.215-18, Reversion or Adjustment of Plans for Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification of Ownership Changes** (October 1997), are deleted in their entirety.
- b. **Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.
- c. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (January 2011), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.
- d. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2011).

4. FAR Clause **52.217-6, Option for Increased Quantity** (March 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within 60 [INSERT THE PERIOD OF TIME IN WHICH THE CONTRACTING OFFICER HAS TO EXERCISE THE OPTION]"

5. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (June 2003).

6. FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996).

7. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2009).

8. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Specific data items that are not subject to paragraph (j) include: None

9. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).

10. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

11. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.242-71, Tobacco-Free Facilities** (January 2006).
2. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (January 2011)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at <http://www.ccr.gov>.

(b)(1) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(2) The Contractor will have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) (i) Public requests for system information prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(ii) As required by section 3010 of Public Law 111-212, all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	Attach1-Packaging&DeliveryProposalNon&DN02-CN-15000-18.pdf
Attachment 2:	Proposal Intent Response Sheet	Attach2-ProposalIntentResponseForm-N02-CN-15000-18.pdf
Attachment 3:	Statement of Work	Attach3-StatementofWorkN02-CN-15000-18.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 4:	Technical Proposal Cost Summary	Attach4-TechnicalProposalCostSummary.pdf
Attachment 5:	Summary of Related Activities	Attach5-SummaryofRelatedActivities.pdf
Attachment 6:	HHS Section 508 Product Assessment Template	Attach6-HHSSection508ProductAssessmentTemplate.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Proposal Summary and Data Record, NIH-2043	Attach7ProposalSummary&DataRecordNIH2043.pdf
Attachment 8:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 9:	Offeror's Points of Contact	Attach9-OfferorsPointsofContact.pdf
Attachment 10:	Disclosure of Lobbying Activities, OMB Form SF-LLL	Attach10-DisclosureofLobbyingActivitiesOMBformSF-LLL.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	Attach11-InvoiceNIH-RC-4.pdf

Attachment No.	Title	Location
Attachment 12:	CommitmentProtectNon-public-infoConAgree(non-disclosure)	Attach12-CommitmentProtectNon-public-infoConAgree(non-disclosure).pdf
Attachment 13:	Roster of Employees Requiring Suitability Investigations	Attach13-RosterEmployeesSuitabilityInvestigations.pdf
Attachment 14:	Employee Separation Checklist	Attach14--Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

which can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions.* As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (*insert page numbers, paragraph designations, etc. or other identification*)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award.*

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

- (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
- (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
- (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
- (iv) A summary of the rationale for award.
- (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
- (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NOTICE OF SMALL BUSINESS SET-ASIDE

1. **General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

c. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is **541690**.
2. The small business size standard is **\$7 Million**.

d. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2011.

It is anticipated that the award from this solicitation will be a multiple-year **Cost Reimbursement** type, **Level of Effort** contract with a Period of Performance of seven (7) years, and that incremental funding will be used. (See Section L.2.c. Business Proposal Instructions).

e. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is **140,000** direct labor hours. It is estimated that the labor hours are constituted as specified below for the seven-years, and shall be expended approximately as follows:

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total Hours All 7 Years
Professional	3,000	3,000	3,000	3,000	3,000	3,000	3,000	21,000
Professional Support	3,500	3,500	3,500	3,500	3,500	3,500	3,500	24,500
Administrative Support	7,500	7,500	7,500	7,500	7,500	7,500	7,500	52,500
Other Support	6,000	6,000	6,000	6,000	6,000	6,000	6,000	42,200
Total Hours	20,000	20,000	20,000	20,000	20,000	20,000	20,000	140,000

Additional Annual Optional Labor Hours

If additional optional hours are required, during the period of performance of this contract, the Contractor shall provide **5,000** direct labor hours each year, for a total of **35,000**, if each additional Labor Hour option is exercised. The labor hours exclude vacation, holiday, and sick leave. These labor hours exclude subcontractor labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1 - Option 1A	Year 2 - Option 2A	Year 3 - Option 3A	Year 4 - Option 4A	Year 5 - Option 5A	Year 6 - Option 6A	Year 7 - Option 7A	Total Option Hours All 7 Years
Professional	750	750	750	750	750	750	750	5,250
Professional Support	875	875	875	875	875	875	875	6,125
Administrative Support	1,875	1,875	1,875	1,875	1,875	1,875	1,875	13,125
Other Support	1,500	1,500	1,500	1,500	1,500	1,500	1,500	10,500
Total Hours	5,000	5,000	5,000	5,000	5,000	5,000	5,000	35,000

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions
National Cancer Institute
Executive Plaza South (EPS) Room 6020
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892- 7195

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. Contract Type and General Clauses

It is contemplated that a cost-reimbursement, level of effort type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a " Technical Proposal" and a " Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

7. Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

10. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

11. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Five years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a dollar value that exceeds \$500,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

12. Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- c. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- d. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).
- e. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. Statement of Work**1. Objectives**

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

a. Sharing Research Data

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

4. **Information and Physical Access Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source.

A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
 1. HHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/121504.html>)
 2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (<http://www.hhs.gov/ohr/manual/pssh.pdf>)

3. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
4. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that (upon award) the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: <http://ocio.nih.gov/docs/public/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations, HHSAR 352.239-70, (January 2010)

- a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows Vista™, including desktops and laptops - regardless of function - but not including servers.

- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://nvd.nist.gov/validation.cfm>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.
- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (see <http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. Standard for Encryption language, HHSAR 352.239-71, (January 2010)

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
 - 1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.
 - 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 - 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
 - 1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

- a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
 - iii. HHS-OCIO Information Systems Security and Privacy Policy.
2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

- b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Technical Representative (COTR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COTR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.
- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
 - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

E. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

a. Information Type:

☐ Administrative, Management and Support Information:

☒ Mission Based Information:

D.19.1 Scientific and Technical Research

b. Security Categories and Levels:

Confidentiality Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

Overall Level: ☐ **Low** ☒ **Moderate** ☐ **High**

- c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COTR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at [Secure One HHS Memorandum on Role-Based Training Requirement](#).

For additional information see the following: <http://ocio.nih.gov/security/security-communicating.htm#RoleBased>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COTR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (<http://ocio.nih.gov/security/nihitrob.html>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

3. **PERSONNEL SECURITY RESPONSIBILITIES**

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COTR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COTR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COTR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf>) when a

Contractor/subcontractor employee terminates work under this contract.
All documentation shall be made available to the COTR upon request.

d. Commitment to Protect Non-Public Departmental Information and Data.

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COTR prior to performing any work under this acquisition.

4. VULNERABILITY SCANNING REQUIREMENTS

This acquisition requires the Contractor to host an NIH webpage or database.

The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (<http://www.sans.org/top20/?ref=3706#w1>). The Contractor shall report the results of these scans to the Project Officer/COTR on a monthly basis, with reports due 10 calendar days following the end of each reporting period.

The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

5. Electronic and Information Technology Accessibility, Section 508 Compliance is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal, entitled, "Section 508 Compliance."

Electronic and Information echnology Accessibility , HHSAR 352.239-73(a) (January 2010)

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--
 1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.
- b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at <http://www.section508.gov/> . The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm> .
 - c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).
 - d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment emplate will be the responsibility of the Contractor and at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

6. Additional Technical Proposal Instructions - Specific to this Project

Technical Approach

Provide comprehensive details of the proposed information management system. The information management system shall be compatible with and be able to migrate to the existing Division of Cancer Prevention (DCP) Enterprise System Knowledge base (DESK).

Provide documentation of appropriate Oracle licenses and any licenses required for literature searching. Provide a detailed work plan indicating how each Task Area of the Statement of Work is to be accomplished. The technical approach should be in sufficient detail to fully explain the proposed approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. In addition, the technical proposal should include information on how the project is to be organized, staff and managed.

Personnel

The Technical Proposal should include all information relevant to document individual education, training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of key technical personnel, including personnel of all proposed subcontractors. The Staffing Plan should include a Personnel Matrix, naming the proposed employees, with indicates the hierarchical line of supervisory authority, and indicate which employee(s) will perform the various tasks. Limit CVs to 2-3 pages and include recent experience with projects of similar size and complexity of the RFP.

1. Principal Investigator/Project Manager

Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Principal Investigator/Project Manager to lead and direct the activities to be carried out under this contract, including: managing personnel and directing work related to information management, understanding multi-disciplinary fields of chemopreventive agent development, overseeing the management of complex, interactive databases, conducting studies to identify new candidates, preparing worksheets for newly selected candidates, and performing reviews of preclinical data and conclusions.

2. Other Key Technical Personnel

Describe the education, training, experience, expertise, qualifications, and percentage of effort for all proposed key technical personnel of the offeror and all proposed subcontractors to carry out the work required in the Statement of Work. Document relevant qualifications in the areas of multi-disciplinary fields of chemopreventive agent development, document and manuscript editing, workshop and meeting planning, complex database management, data management, object oriented development, quality control, preparation of Investigational Drug Brochures, knowledge of TestTrack Pro or comparable tool, J2EE, web services, XML, ANSI compliant SQL and Eclipse, Enterprise or other project management timeline software, and Microsoft Access or similar software.

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

3. Data Other than Certified Cost or Pricing Data

- a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

- b. The data submitted shall be at the level of detail described below.

a. Direct Labor

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

b. Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

c. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

d. Raw Materials

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

e. Purchased Parts

Includes material items not covered above. Provide priced quantities of items required for the proposal.

f. Fringe Benefits

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

g. Indirect Costs

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

h. Special Equipment

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

i. Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

j. Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

4. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

5. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

6. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).*
- (2) The offeror's name and remittance address, as stated in the offer.*
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.*
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.*
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).*
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.*
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.*

(End of Provision)

c. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. Incremental Funding

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

Incremental Funding, HHSAR 352.232-70 (June 2010)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds," and 352.232-71, "Estimated Cost - Incrementally Funded Contract." The initial obligation of funds under the contract is expected to cover TBD after negotiations. The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

e. **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

☐ **Fac Cap Cost of Money (Has)** The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

☐ **Fac Cap Cost of Money (Has Not)** **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

7. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

8. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

9. Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

10. Travel Costs/Travel Policy**a. Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

11. Additional Business Proposal Instructions - Specific to this Project

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.

TRAVEL

- a. Assume two (2) staff members will attend, make presentations, and prepare meeting summaries/reports/minutes for approximately four (4) Chemopreventive Agent Development Working Group meetings per year to be held in Rockville, MD. This meeting will last one (1) day and require one (1) overnight stay.
- b. Assume two (2) staff members will attend two (2) scientific meetings per year (includes registration fee). Since these sites have not been determined at this time, please budget for two (2) 5-day meetings per year, and assume on destinations to the following: **East coast - Washington, DC , Midwest - Chicago, IL, and West coast - San Francisco, CA** , and average the cost per meeting based on the three areas.
- c. Assume two (2) staff members will provide technical support for up to two (2) one-day workshops per year on strategy development for chemoprevention which shall include assistance in program planning, list of invitees, and receipt and editing of manuscripts. The workshops will last one (1) day with one (1) overnight stay and have 12 investigators and 12 DCP attendees will participate. The workshops will be held in Rockville, MD.
- d. Assume one (1) staff member will provide technical support for two (2) Chemopreventive Agent Development Special Emphasis Panel review meetings per year. The meeting will last one (1) day with one (1) overnight stay and 15 reviewers and 4 CADRG attendees will participate. These meetings will be held in Rockville, MD.

TASK AREA #1

Assume the following:

1. Conduct three (3) chemical class studies, e.g., non-steroidal anti-inflammatories, hormone receptor agonists / antagonists, per year to identify candidate agents for testing.
2. Conduct five (5) structure-activity studies will be performed in the first year and five (5) in each of the following years.
3. Document 20 candidate agents per year based on documented criteria as described in the Statement of Work
4. Prepare 50 worksheets per year on newly selected candidate agents and on any other agents in the CADRG testing program for which such documentation does not exist.

TASK AREA #2**Assume the following:**

1. Maintain the Master List Agent (Desktop) Databases in the agent development information system DESK (see system specifications under Task #3) which currently has 23,647 records.
2. Review and document five (5) new assays, models, and intermediate endpoints per year being considered for the DCP CADRG testing programs.
3. Develop 50 Enterprise (or other software) project management time lines for all agents in development including anticipated testing requirements, test results, milestone go/no go decision points, etc. to aid in planning and tracking for preclinical and clinical testing.
4. Provide content for four (4) new INDs per year and 30 continuing INDs (annual reports) will be supported.
5. Prepare four (4) sets of presentation graphics in PowerPoint and four (4) reviews for publication per year.
6. Prepare six (6) Clinical Development Plans per year, addressing rationale for evaluation, supportive preclinical efficacy and biomarker data, preclinical safety and toxicity data, clinical experience, availability, and other topics as appropriate.
7. Prepare appropriate content for two (2) new Investigational Drug Brochures each year. Update three (3) existing Investigational Drug Brochures each year.
8. Maintain Clinical Testing Database which currently contains 11 tables and 5399 records.
9. Maintain the Chemopreventive Agent Chemistry Database containing naming, structure, and other information on agents in DCP's preclinical and clinical testing program which currently contains 10,370 records on 4900 agents.
10. Prepare five (5) agent announcements twice a year based on existing worksheets, agent development plans, investigational drug brochures, and decisions reached by the Chemopreventive Agent Development Management and Administrative Committee.
11. Provide background information about agents proposed in unsolicited letters of intent(20 per year).
12. Per month, perform ten scientific reviews of chemoprevention concepts, letters of intent, protocols, protocol revisions, and amendments.

TASK AREA #4

Assume that editorial services for 10 documents generated by the CADRG each year will be provided to include internal reports for the DCP Director, public relations reports such as brochures and web based reports for the CADRG website.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

3. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

5. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

A. Technical Approach Weight 30%

Demonstrated understanding of technical, and operational challenges and issues associated with accomplishing the required Statement of Work. Appropriateness, adequacy, quality, clarity, soundness and feasibility of the technical approach with respect to:

1. Approach to accomplishing the tasks described in the Statement of Work and demonstrated understanding of the objectives and requirements of the RFP.
2. Approach to coordination and interaction with the Division of Cancer Prevention (DCP) and National Cancer Institute (NCI) staff to accomplish tasks.
3. Methodology for conducting studies to identify new candidates, preparing worksheets for newly selected candidates, and performing reviews of preclinical data and conclusions.
4. Approach for database updating and management, including database support, statistical approaches and overall information management.
5. Approach for quality assurance and quality control of all data and procedures.
6. Suitability of plans for use of consultants and/or subcontractors, if necessary.

B. Personnel Weight 30%

1. Appropriateness and adequacy of the education, training, experience, expertise and effort of the proposed Principal Investigator/Project Director with respect to the following:
 - a. Managing personnel and directing work related to information management in science related areas.
 - b. Understanding multi-disciplinary fields of chemopreventive agent development.
 - c. Overseeing the management of complex, interactive databases.
 - d. Conducting studies to identify new candidates, preparing worksheets for newly selected candidates, and performing reviews of preclinical data and conclusions.
2. Appropriateness and adequacy of the training, experience, expertise and level of effort of other proposed technical personnel of the offeror and all proposed subcontractors, including the adequacy of the proposed mix of staff, expertise, experience, and training to carry out contract requirements with respect to the following:

- a. Multi-disciplinary fields of chemopreventive agent development.
- b. Document and manuscript editing, workshop planning, and meeting planning.
- c. Complex database management, data management, and quality control.
- d. Preparation of Investigational Drug Brochures.
- e. Knowledge of TestTrack Pro or comparable tool, J2EE, web services, XML, ANSI compliant SQL and Eclipse, Enterprise or other project management timeline software, and Microsoft Access or similar software.

C. Organizational Experience Weight 30%

Demonstrate the organizational experience and capability as needed for the performance of the tasks stated in the SOW, including:

- 1. Suitability of the organization's past experience and current activity in each of the project areas of the Statement of Work.
- 2. Documentation of the organization's experience relative to the size and scope of the work in the RFP.
- 3. Documented evidence of problem solving skills, creativity, and improved outcomes in current or past work similar to the Statement of Work.
- 4. Documented experience in maintaining data security and confidentiality.

D. Facilities and Resources Weight 10%

- 1. Documented availability of adequate facilities, equipment, resources and secure storage of documents and databases to perform the Statement of Work
- 2. Availability of state-of-the art database management system and internet access.
- 3. Adequacy of available facilities and equipment to conduct information management services.
- 4. Secure facilities for the storage and protection of hard copy data, magnetic/optical storage media, and archival material.

6. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

7. PAST PERFORMANCE FACTOR

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.